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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,086

06/21/2005

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24628 7590 09/12/2008

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EXAMINER

JARRELL, NOBLE E

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

09/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,086	Applicant(s) GUNNING ET AL.	
	Examiner Noble Jarrell	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-33 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 and 24 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 12, 20-22, 25-29 and 32 is/are rejected.
- 7) ☒ Claim(s) 10, 11, 13-19, 30, 31 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/5/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. The objection to the IDS has been overcome by the amendment filed 5/5/2008.
2. The rejection under 35 U.S.C. 112 2nd paragraph regarding claims 1-4 and 6-19 has been overcome by the amendment filed 5/5/2008.
3. The rejection under 35 U.S.C. 103 regarding the reference of Wiebe et al. has been overcome by the amendment filed 5/5/2008.
4. The rejections under 35 U.S.C. 102 regarding the references of Wiebe et al., Tal et al., and Tochtrop et al. have been overcome by the amendment filed 5/5/08.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 20-22, 25, 27-29, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "derivative" in the claims refers to esters and salts (page 5, lines 14-22). At which position is the ester attached to the sapogenin? Applicants show an ester at the 3-position on page 9 in the compound smilagenin benzoate, but the ester as it is claimed currently could be attached at any point on the molecule, not just the 3-position. In an analysis of claim 13 (the perceived intended structure), the ester could be at any one of 6 points of attachment. Claims 21, 22, and 25, even though they were not rejected in the first action, still depend on claim 20, which has not been amended to overcome the rejection under 35 U.S.C. 112, 2nd paragraph. Hence, this rejection is maintained.

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Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 6-9, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Gondos et al. (*Journal of the Chemical Society, Chemical Communications*, **1982**, 1239-40). Gondos et al. teach the reduction of 5 β -andosterone-3, 17-dione and 5 β -pregnane-3,20-dione with K-Selectride (potassium tri-sec-butylborohydride). Claims 1-2 and 6-7 are anticipated because the hydroxyl is formed and the major product is the 3 β product. Claims 3-4 are anticipated because the reducing agent is K-Selectride. Claims 8-9 are anticipated because THF is the solvent used. This rejection is maintained because the definition of a sapogenin (Smith et al. *Oxford Dictionary of Biochemistry and Molecular Biology*, **1997**, page 584) is an aglycon moiety of a steroidal sugar. One of ordinary skill in the art can conclude that any steroid with a sugar moiety can be considered as a substrate for the process of claims 1-3, 6-9, and 26. For the reasons cited, the rejection is maintained.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 4, 12 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gondos et al. (*Journal of the Chemical Society, Chemical Communications*, **1982**, 1239-40. Gondos et al. teach the reduction of 5 β -andosterone-3, 17-dione and 5 β -pregnane-3,20-dione with K-Selectride. Claim 4 is rendered obvious because lithium is 1A element like potassium, and the replacement of one for the other will not affect the reduction. Claim 12 is rendered obvious because 2-methyl-tetrahydrofuran and THF share the same core structure, and hence the substitution of one for the other is obvious. This rejection is maintained because the definition of a sapogenin (Smith et al. *Oxford Dictionary of Biochemistry and Molecular Biology*, **1997**, page 584) is an aglycon moiety of a steroidal sugar. One of ordinary skill in the art can conclude that any steroid with a sugar moiety can be considered as a substrate for the process of claims 4, 6-7, 12 and 26. For the reasons cited, the rejection is maintained.

Allowable Subject Matter

12. Claims 23 and 24 allowed.

13. Claims 10, 11, 13-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter: Gondos et al. (*Journal of the Chemical Society, Chemical Communications*, **1982**, 1239-40.

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Gondos et al. teach the reduction of 5 β -andosterone-3, 17-dione and 5 β -pregnane-3,20-dione with K-Selectride (potassium tri-sec-butylborohydride). The starting substrate used by Gondos et al. does not anticipate or render obvious a process of claims 13-19, 23, or 24 because an acetyl group is not considered an analogue of a spiro-pyran ring. THF is not considered an analogous solvent to toluene or 1,4-dioxan because the ring systems are different for each of these solvents.

Claim Objections

15. Claims 30-31 are objected to under 37 CFR 1.75(c) as being in improper form because each of these claims are each an improper multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

16. Claim 33 is objected to because of the following informalities: it refers back to itself, and in addition, refers to claim 34, which is not present in the amended set of claims. Thus, it has not been acted on. Appropriate correction is required.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Examiner, Art Unit 1624

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**